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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/929,666	Applicant(s) ANDERSON ET AL.	
	Examiner Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *5-12 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 13-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6&10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election acknowledged

Applicants affirmation on the election with traverse of Group I, claims 1-4, 17-21 is acknowledged. It is noted that there is a typographical error made in the previous office action wherein the claims 13-16 were left out inadvertently from the grouping resulted from restriction practice. Since the subject matter of the claims 13-16 were commonly shared by group I and II, the examiner will include the claims 13-16 into the elected group I, and the claims 1-4 and 13-21 will be presented for the examination.

Applicant's election is made without traverse. The requirement is deemed to be proper and is therefore made FINAL.

Status of Application

The claims 1-25 are pending and the elected claims 1-4 and 17-21 are presented for the examination. The non-elected claims 5-16, 22-25 are withdrawn from the consideration.

Information Disclosure Statement

Applicant's information disclosure statement received 12/03/01 and 08/08/03(paper no. 6 & 10) has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 17-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating the symptoms claimed using a heterocyclic amine of the formula I claimed(recited in claims 2-4), does not reasonably provide enablement for a method of treating the symptoms claimed using all the heterocyclic amines excluding the heterocyclic amine of the formula I claimed(recited in claims 2-4). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

For rejections under 35 USC 112, first paragraph, the following factors must be considered(In re Wands, 8 USPQ2d 1400, 1404 (CaAFC, 1988)):

1) Nature of invention

2) State of prior art

3) Level of ordinary skill in the art

4) Level of predictability in the art

5) Amount of direction and guidance provided by the inventor

6) Existence of working examples

7) Breadth of claims

8)Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention

Instant invention is directed to a method of treating or suprresiing the symptoms of at least one disorder selected from addictive disorders using the therapeutically effective amount of heterocyclic amines such as a heterocyclic amine of the formula I that is recited in claims 2-4.

2) State of the prior art.

The references cited in the application(instant specification at page 1, lines 25-35) teaches about how to make and use heterocyclic amine compound having the claimed formula I, and the use thereof.

However, numerous other heterocyclic amine compounds that does not have same hetero amine moiety as required by the instant claims are not used in the treatment of the symptoms of addictive disorders or are used to treat materially different disorders .

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high.

4) Level of predictability in the art.

The unpredictability of the pharmaceutical art is very high. In fact, the courts have made a distinct between mechanical elements function the same in different circumstances, yielding predictable results, chemical and biological compounds often react unpredictably under different circumstances. Nationwide Chem.Corp.v.Wright, 458F. Supp. 828, 839, 192 USPQ 95, 105(M.D. Fla. 1976); Aff'd 584 F.2d 714, 200 USPQ 257(5th Cir. 1978); In re Fischer, 427 F 2d 833, 839,166 USPQ, 10, 24(CCPA 1970). The art pertaining to the physiological and pharmacological activity of a chemical or biological compound is considered to be highly unpredictable.

5) Amount of direction and guidance provided by the inventor.

The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. In re Fischer, 839, 166 USPQ 24. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. In re Fischer 427 F 2d 839, 166 USPQ 24; Ex Parte Hitzeman, 9 USPQ 2d 1823.

For example, the Federal circuit determined that, given the unpredictability of the physiological activity of viruses or microorganisms, a specification requires more than a general description and a single embodiment to provide an enabling disclosure for a method of protecting an organism against virus or microorganism infection. In re Wright, 999 F 2d 1562-63 USPQ2d 1575.

In the instant case, given the unpredictability of the physiological or pharmaceutical activity of heterocyclic amines, the specification provides no guidance, in the way of enablement for making such heterocyclic amine compounds that do not have same heterocyclic amine moity of the formula I and for use them.

Furthermore, the specification provides no guidance, in the way written description for numerous other heterocyclic amines that are compassed by the generic formula I claimed. This is because it is not obvious from the disclosure of one species, what other species will work. In re Richfield, 110 Fed 235, 45 USPQ 36(CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included

in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Caswa," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail.

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of claims will possess the alleged activity.

6) Existence of working examples.

As stated above, the specification does not disclose any working examples of the heterocyclic amines that do not have same heterocyclic amine moiety. The working examples are limited to the heterocyclic amine compounds

7) Breadth of claims.

The claims are extremely broad due to the vast number of heterocyclic amine compounds that are obtained from numerous substitution with different synthetic process.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The quantity of experimentation needed to be performed by one skilled in the art is yet another factor involved in the determining whether "undue experimentation" is required to make and use the instant invention. " The test is not merely quantitative since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." In

re Wands, 858 F. 2d 737, 8 USPQ2d 1404(citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 218 (CCPA 1976)). The skilled artisan would have a numerous amount of modifications to perform in order to obtain substituted compounds as claimed. For these reasons, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine all the possible substitution of the alcohols and carboxylic acids that would be enabled in this specification.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see In re Armbruster 185 USPQ 152 CCPA 1975.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 and 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own claim languages to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "psychoactive substance use disorders, inhalation disorders or intoxication disorders" in claim 1 is used by the claim

to mean "disorders caused by psychoactive substance overuse, inhalation overuse or intoxication", while the accepted meaning is "disorders requiring psychoactive substance use, inhalation use or disorders causing intoxication, respectively." The term is indefinite because the specification does not clearly redefine the term.

Allowable Subject Matter

3. The claims 2-4 and 17-21 contain the allowable subject matter. The allowable subject matter is the method of treating the symptoms of addictive disorders wherein the said disorder is alcohol addiction, tobacco addiction or nicotine addiction, said method comprising the step of administering a therapeutically effective, nontoxic amount of an active agent wherein the active agent is a heterocyclic amine of the formula I(recited in claim 2), and pharmaceutically acceptable derivatives or salts thereof, to a patient in need of treatment.

4. The allowable subject matter indicated immediately above is not taught by or obvious over any prior art of the record.

Conclusion

1. No claim is allowed.

2. Claims 2-4 and 17-21 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the

examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
August 29, 2003
Art unit 1614